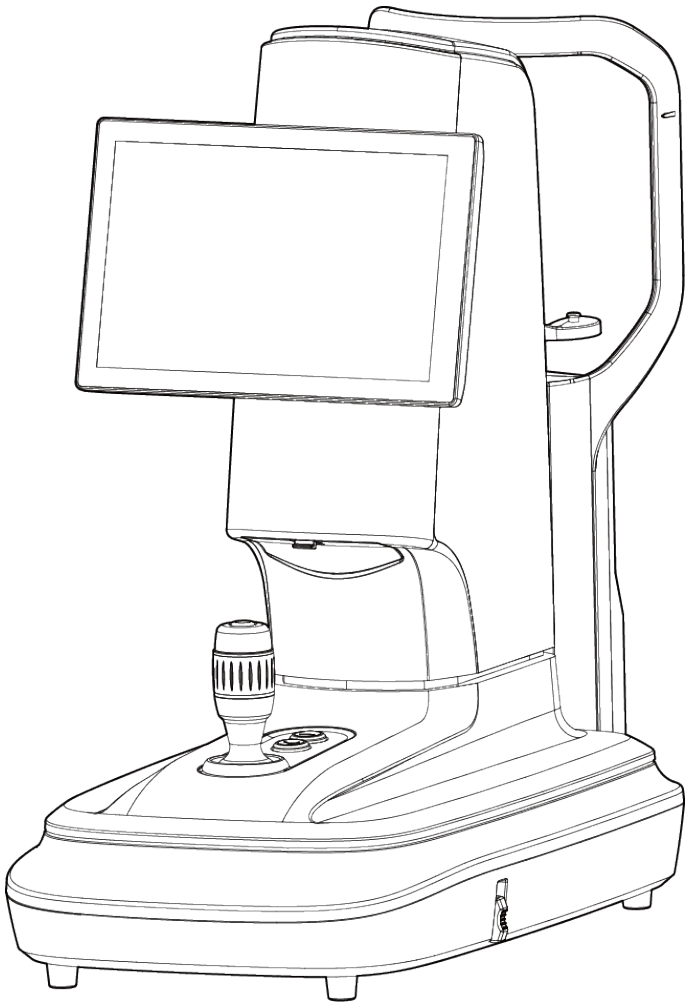
User Manual of DEA 520 Corneal Topographer



Shanghai MediWorks Precision Instruments Co., Ltd

Contents

1. Overview

1.1. Preface

Thank you for choosing DEA520 corneal topography system of Shanghai MediWorks Precision Instrument Co., Ltd.

- This manual is an integral part of the whole set of product, and the relevant application as well as technical instructions and technical is provided. The addresses for user inquiries are recorded on the last page of the manual.
- This manual consists of the instrument usage and technical part. The equipment classification required by the product according to the IEC 60601-1-1:2000 is also shown in this manual.
- The intended use of product is for the measurement of the curvature of the corneal surface.

1.2. The Main Parameters

Projection ring diameter	Far-distance mode: 8.8mm (43D)
	Close-distance mode: 11mm (43D)
Radius of curvature	32.14 dpt～ 61.36 dpt (5.5mm~10.5mm) Precision: ±0.1 dpt (±0.02mm)
White-to-white range	6～17mm Tolerance：±0.1mm
Astigmatism axis	0～180° Tolerance: the difference in the radius of curvature of the principal meridian axis≤0.3 mm: ±4°
Pupil diameter	1～13mm

1.3.

	Tolerance: ±0.1mm
Topography function	Sagittal curvature Tangential curvature Elevation map (best fit sphere, ellipsoid) Refractive power map
Four Maps	Four types of topographic map display
Shape factor	E, Ecc, P, Q values in each direction within the range of diameter 2-10mm
Aberration	Corneal wavefront aberration in different pupil diameters, PSF map, MTF curve, patients' vision quality simulation map
Comparison of inspection results	Support 2 results comparison, difference comparison on topographic map
Display screen	10.1 inch touch screen
Left and right eye (OD&OS)recognition	Automatic

Weight and Dimensions

Dimensions: 53cm x 30cm x 54cm

Weight: 12.7 kg

1.4. Device operating environment

Temperature: -5 ℃ ~ + 40 ℃

Relative humidity: ≤ 80% , No Condensation

Atmospheric pressure: 800hPa ~ 1060hPa

1.5. Storage Environment

Temperature:-40 ℃ ~ + 55 ℃

Relative humidity: ≤ 90%, No Condensation

Atmospheric pressure: 700hPa ~ 1060hPa

1.6. Transportation Environment

Temperature: -40 ℃ ~ + 55 ℃

Relative humidity: ≤ 90% , No Condensation

Atmospheric pressure: 700hPa ~ 1060hPa

1.7. Description of Icons, Symbols and Warning Labels on Products

According to IEC 60601-1:2005, the following figures, symbols and marks are used on DEA520,For the specific meanings, see Table 1 as below

Table 1:

No.	Mark	Description
1		Type B.
2		Date of production.
3		WEEE logo. Please dispose of the waste generated by the machine according to local laws and regulations.
4		CE Mark.
5		Located on the power switch, it indicates that the main power is on.
6		Located on the power switch, it indicates that the main power is off.

1.8. Marks of DEA520

DEA520 is a device that uses network power supply. According to the requirements of the IEC 60601-1:2005 standard, the following external marks are used. These marks will be permanently pasted on the outside of the device. The following tips in Table 2 can be your reference when you use our device

Table 2:

No.	Content	Description
1	Manufacturer/Supplier	Shanghai MediWorks Precision Instrument co., ltd
2	Figures/Symbols/Marks	Details in Table 1
3	Power	Input:-100 ~ 240V, 50/60 Hz
4	Rated power	240VA
5	Power output of network power supply	Not applicable
6	Classification	Class I electrical equipment
7	Working system	Continuous working system
8	Physiological effect	Unmarked, not applicable
9	AP/AGP class equipment	Unmarked, not applicable
10	High-voltage terminal device	Unmarked, not applicable
11	Cooling condition	Unmarked, not applicable
12	Mechanical stability	Unmarked, the equipment shall not be placed on an inclined plane with an inclination greater than 10°
13	Protective packaging	The symbols marked on the outer packaging of the equipment according to the standard of ISO 780 Packaging, Storage and Transportation Illustration Mark, including "Up", "Fragile", "No Wet", "Limit of Stacking Layers" and "Limit of Stacking

		Weight", etc.

1.9. Indicator Light

The power switch is a switch with indicator light. When it is bright in green, it indicates that the power supply is turned on and the equipment is running.

The power switch is designed with indicator light. When the light is green, it means the power is on and the device is working.

⚠ **General Requirements for Safety**

Dear customers, please read the instruction manual carefully before using our products to avoid accidental mechanical hazards and improper use of the user, resulting in unclear images and diagnostic errors. In particular, carefully read the following safety precautions to prevent the product is damaged, personal injury, and other hazards and accidents that may occur.

- The product can only be used by qualified medical staff.
- Do not disassemble or attempt to perform operations that are not described in this instruction manual. If the operation is not performed properly, excessive force may cause damage to the machine or personal injury. If the instrument fails, please read the troubleshooting guide carefully; follow the troubleshooting methods and steps to troubleshoot the problem; if the problems remain unsolved, please contact our Manufacturer and Service Department, and our company will arrange professional maintenance personnel to help you troubleshoot.
- Do not store and use in a flammable, explosive, high temperature, high humidity and dusty environment; use it in a clean room, keeping the product clean and dry.
- Other medical instruments and equipment that installed at the same site must comply with the same electromagnetic compatibility principles. Equipment that cannot comply with or is known to have poor electromagnetic compatibility must be installed at least 3 meters away from the equipment and must be powered by a different power cord.
- Please pay attention to the rating of all electrical connection ports.

- Before using the instrument, please check all the wires are correctly connected; if the wires are inappropriately connected it may cause the instrument to be short-circuited, which may cause the product is damaged and personal injury.
- Users should pay attention when using the instrument, and be careful when moving the parts to avoid damage due to the moving of the base and tilting of the projection tube.
- When replacing fuses and other electrical components, turn off the main power switch. Replace the fuse that meets the specifications specified in this manual.
- If there is a need to replace power cord, please use the power cord specified in this manual.
- Don’t touch the surface of the lens and prism with hand or hard objects.
- When the device is not operating, the power should be turned off, and cover the device with dust cover.
- To prevent the instrument from falling down to floor, it should be placed on the floor where the inclination angle is less than 10°.
- Please deal with the waste disposal produced by the machine following relevant laws and regulations.
- Please read the safety signs and other illustrations used on this instrument carefully to use the device safely.

1.10. Electromagnetic Compatibility Information

- For DEA520, it is essential to take special precautions related to electromagnetic compatibility (EMC). Moreover, it must be installed and used in accordance with the electromagnetic compatibility information specified in this manual.
- Portable and mobile radio frequency communication equipment may affect this equipment.
- The use of accessories and cable other than those specified, with the exception of accessories and cables sold

Of DEA520 as replacement parts for internal components, may result in increased EMISSIONS or

decreased IMMUNITY or decreased LIFESPAN of the DEA520

- DEA 520 should not be used in close proximity or in stack with other equipment. If it must be used in close proximity or in stack, it should be observed to verify that it can operate normally in the configuration in which it is used.

Guidelines and Manufacturer's Statement-Electromagnetic Emission DEA520 is intended to be used in the following specified electromagnetic environments, and the purchaser or user shall ensure that it is used in such electromagnetic environments:		
Emissions test	Conformity	Electromagnetic environment-guidelines
Radio frequency emission CISPR 11	Group 1	The DEA520 uses RF energy only for its internal functions, so that its RF emission is very low and there is little possibility of interference to nearby electronic devices
Radio frequency emission CISPR 11	Class A	DEA520 is applicable for all facilities that are not used for home and are not directly connected to the public low-voltage power supply network of domestic residences.
Harmonic radiation IEC 61000-3-2	N/A	
Voltage fluctuation/flicker emission IEC61000-3-3	N/A	

Guidelines and Manufacturer's Statement-Electromagnetic Immunity
DEA520 Apparatus is intended to be used in the following specified electromagnetic environments, and the purchaser or user shall ensure that it is used in such electromagnetic environments:

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guideline
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact discharge ± 8kV air discharge	± 6kV contact discharge ± 8kV air discharge	The floor shall be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity shall be at least 30%.
Electrical fast transient pulse group IEC 61000-4-4	± 2kV pair power cord ± 1kV pair of input/output lines	± 2kV pair power cord	The grid power supply should be of typical quality used in commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line-to-line ± 2kV line to ground	± 1kV line-to-line ± 2kV line to ground	The grid power supply should be of typical quality used in commercial or hospital environment.
Voltage sag, short interruption and voltage change on power supply input line IEC 61000-4-11	< 5% UT for 0.5 cycles (> 95% sag on UT) 40% UT for 5 cycles (60% sag on UT) 70% UT for 25 cycles (on UT, 30% sag) < 5% UT for 5s (> 95% sag on UT)	< 5% UT for 0.5 cycles (> 95% sag on UT) 40% UT for 5 cycles (60% sag on UT) 70% UT for 25 cycles (on UT, 30% sag) < 5% UT for 5s (> 95% sag on UT)	The network power supply should be of the quality used in a typical commercial or hospital environment. If the user of the DEA520 needs continuous operation during the power interruption, it is recommended that the DEA520 uses uninterrupted power supply or battery power supply.
Power frequency magnetic field	3 A/m	3 A/m	The power frequency magnetic field should have the horizontal

(50/60 Hz) IEC 61000-4-8			characteristics of the power frequency magnetic field in typical places in typical commercial or hospital environments.
Note: UT refers to the AC network voltage prior to the application of the test voltage.			

Radio frequency conduction IEC 61000-4-6 Radio frequency radiation IEC61000-4-3	3 V (RMS) 150kHz-80MHz 3 V/m 80MHz-2.5 GHz	3 V (RMS) 3 V/m	Portable and mobile RF communication equipment shall not be used closer to any part of the equipment, including cables, than the recommended isolation distance. The distance is calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance $D = 1.2\sqrt{p}$ 150kHz-80MHz $D = 1.2\sqrt{p}$ 80MHz-800MHz $D = 2.3\sqrt{p}$ 800MHz-2.5 GHz Where: P-based on the transmitter

			manufacturer's maximum rated output power, in watts (W); D-denotes the recommended isolation distance, in meters (m). The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field [a] and should be lower than the coincidence level in each frequency range [b]. Interference may occur close to devices marked with the following symbols. 

Note 1: At 80MHz and 800MHz frequencies, the formula of higher frequency band is adopted.

Note 2: These guidelines may not be appropriate for all cases, where electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.

a: The field strength of fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts and television broadcasts, cannot be accurately predicted. In order to evaluate the electromagnetic environment of fixed RF transmitter, the survey of electromagnetic field should be taken into account. If the measured field strength of the DEA520 apparatus is higher than the above-mentioned applicable RF coincidence level, the DEA520 apparatus should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorientation or position of DEA520 instrument.

b: In the whole frequency range from 150kHz to 80MHz, the field strength

should be lower than 3V/m.

Recommended isolation distance between portable and mobile radio frequency communication equipment and DEA520 instrument

DEA520 is expected to be used in electromagnetic environments, where RF radiation disturbance is controlled. According to the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitter) and DEA520 instrument recommended below.

Maximum rated output power of transmitter W	Isolation distance corresponding to different frequencies of transmitter/m		
	150kHz-80MHz $D = 1.2\sqrt{p}$	80MHz-800MHz $D = 1.2\sqrt{p}$	800MHz-2.5 GHz $D = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

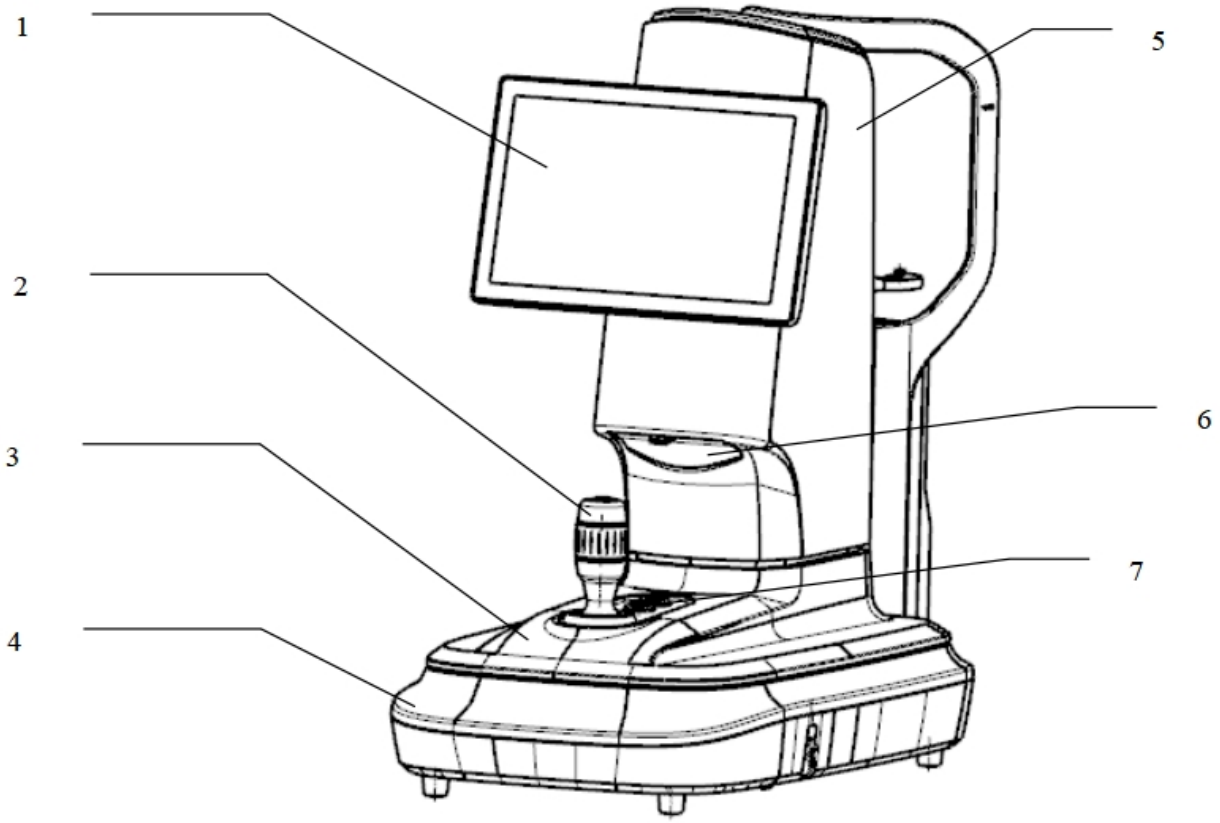
For the maximum rated output power of transmitter not listed in the above table, the recommended isolation distance D, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P refers to the transmitter maximum rated output power provided by the transmitter manufacturer. In watts (W).

Note 1: At 80MHz and 800MHz frequency points, the formula of higher frequency band is adopted.

Note 2: These guidelines may not be appropriate for all cases, where electromagnetic propagation can be affected by absorption and reflection from buildings, objects and the human body.

2. Product Composition

2.1. Illustration of each part



1. Touch screen

2. Control handle

Tilting handle can make the instrument move slightly in the horizontal plane. Besides, rotating handle can adjust the instrument to move up and down in a small range, and pressing shutter can control the instrument for scanning.

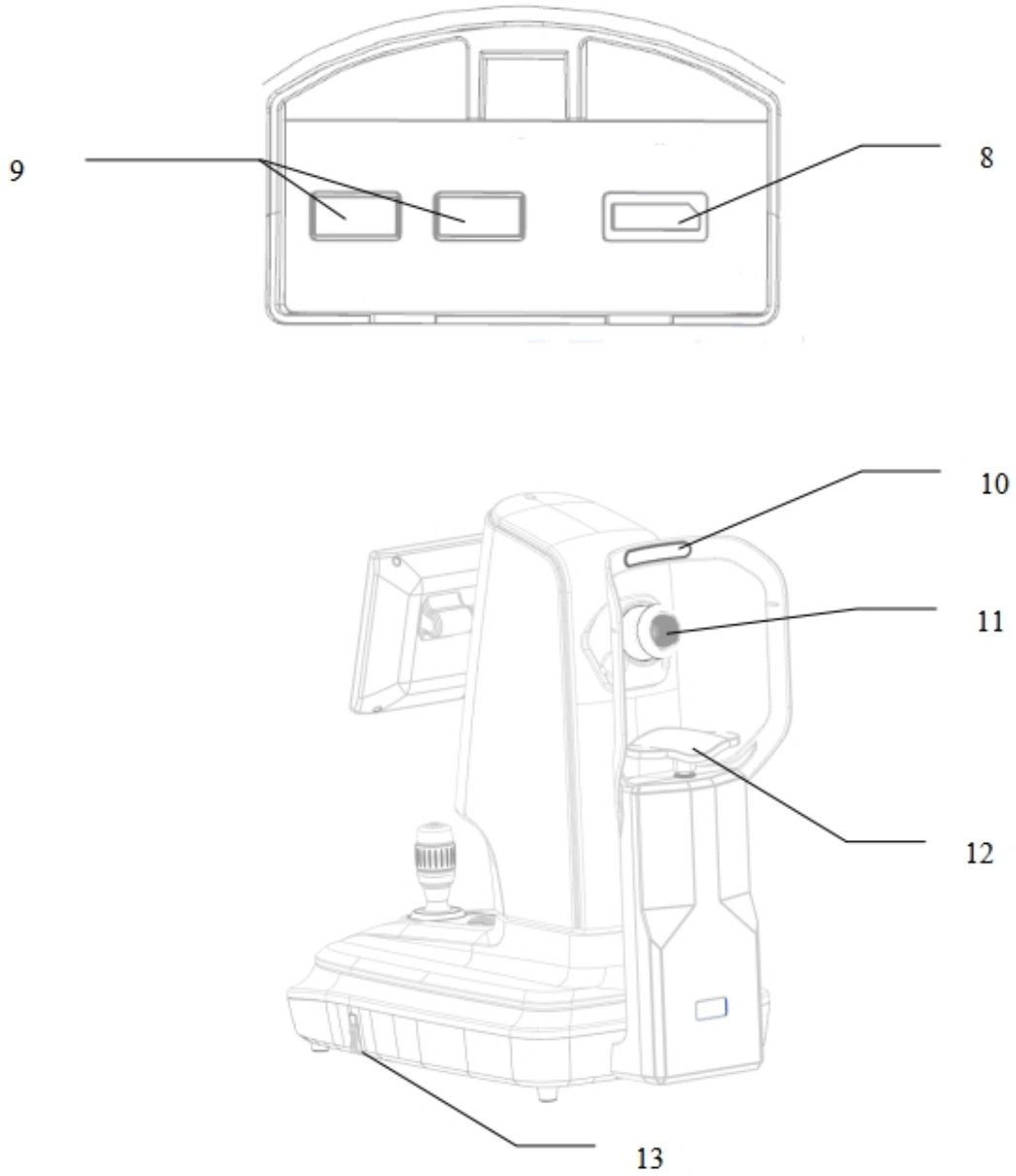
3. Movement Platform

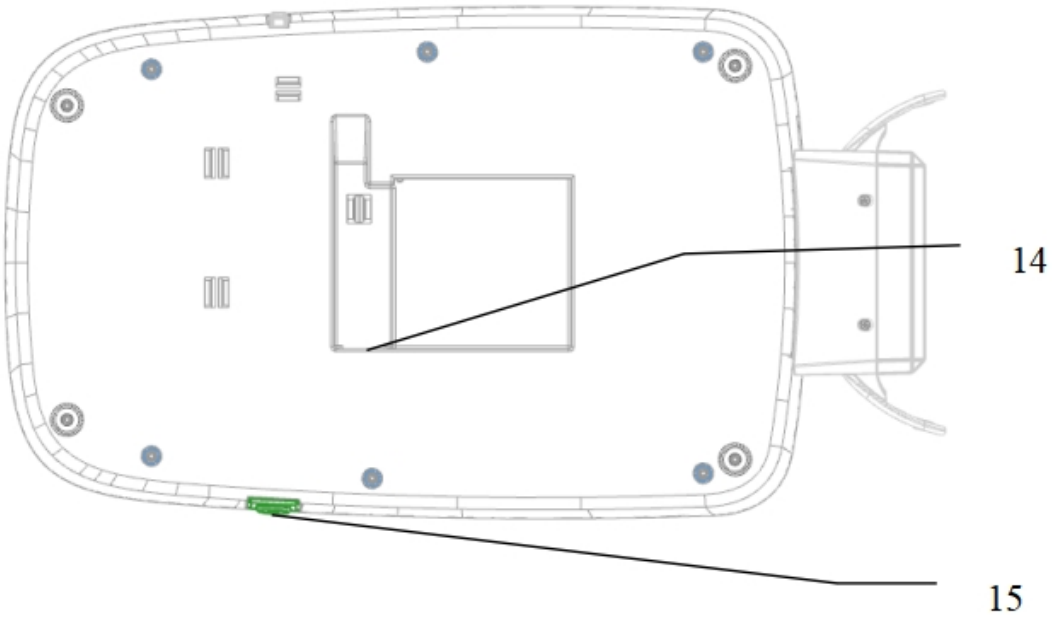
4. Base

5. Main shell

6 Interface cover plate

7 Chin-rest lifting button





8. Video data cable interface

One end of the video data cable is inserted into the DP hole, and another is inserted into the DP hole of the display screen. The screen can be expanded after connecting the video data cable.

9. USB interface

You can insert U drive and USB data cable to export and import data.

10. Forehead belt keeps the patient's head in the right position.

11. Placido ring

12. Chin rest, supporting the patient’s chin.

13. Lock button

14. Power plug

15. Power switch

2.2. Unpacking Checklist

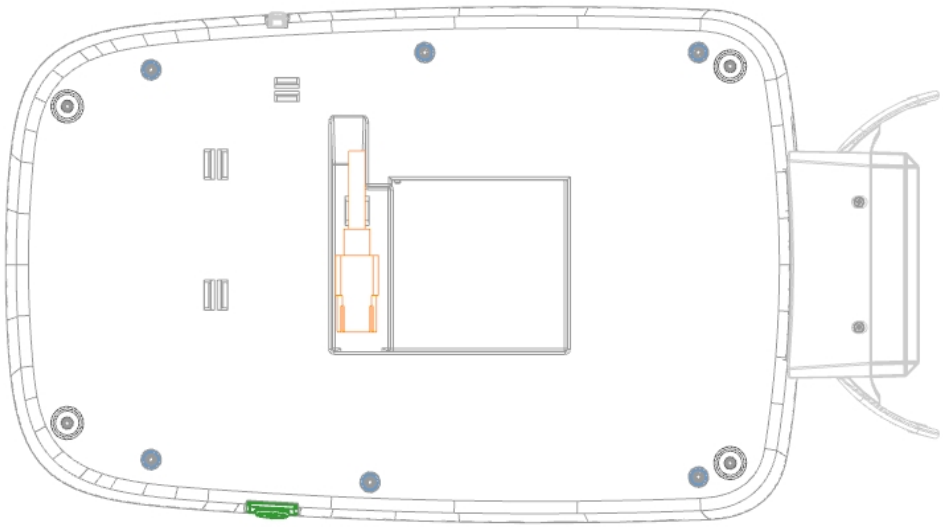
No.	Part Name	Qty.
1.	DEA520	1
2.	Power Cable	1
3.	Model Eye	1
4.	Chin-rest Paper	1
5.	Dust Cover	1
6.	Video Data Cable	1

2.3. Product Installation

1. Carefully remove the equipment and place it on the table top (shown as below), and plug in the power Cable attached with it;

2. Pull down the lock button so that the device is in a movable state.

3. Press the power switch, then wait the power indicator lights up and the equipment starts up. To turn off the device,,you can press the power switch button and the device will turn off automatically.

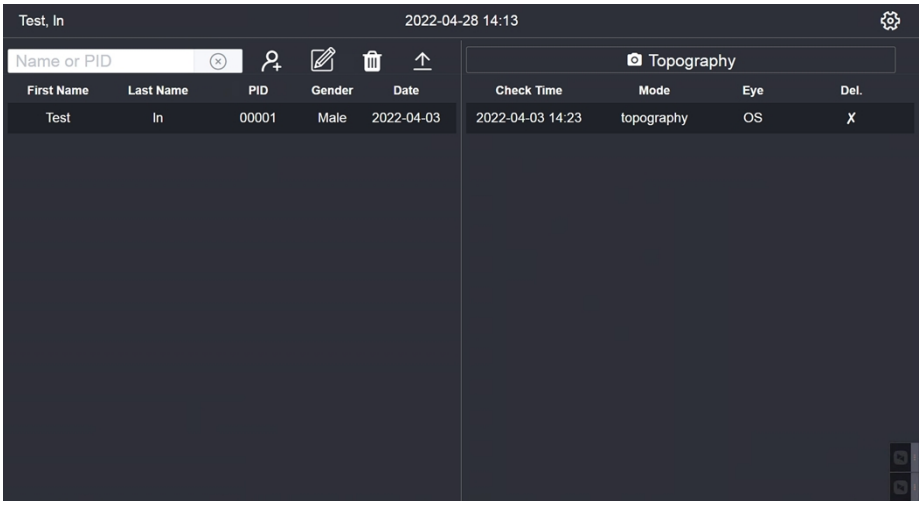


3. Software Function

Notice: All the data and images in the following interface can only be used for functional description, they cannot be used as diagnostic proof or reference.

3.1. Patient Information and Patient record management

Enter the patient and case management interface (shown as below).



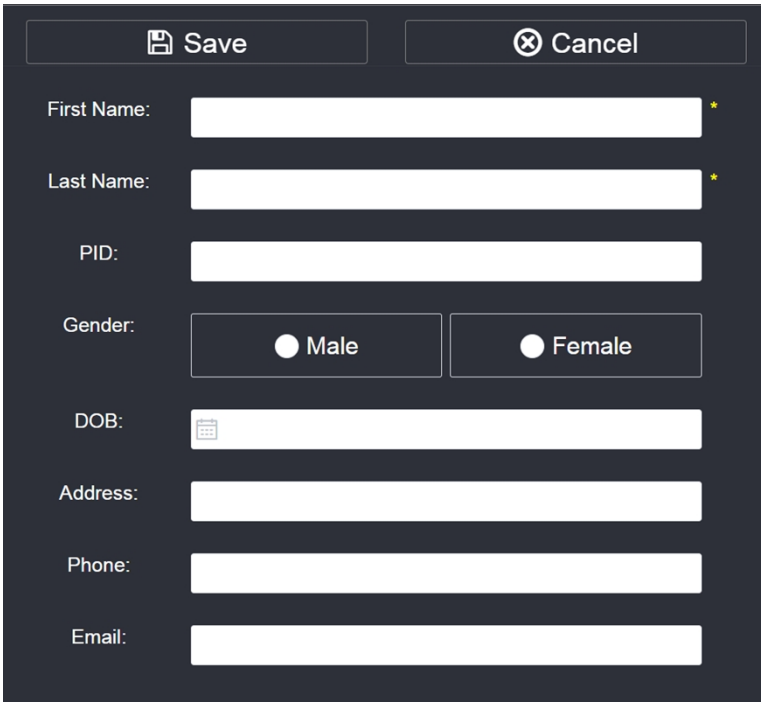
The left side of the interface is the patient management, and the right side is the case management.

- Patient information search: Enter the name or Patient ID 

in

the search box for patient information searching

● Add patient: Click the Add button  to enter the patient information editing interface (shown as below).



Input the patient's relevant information in the interface and click the "OK" button to save . Click the “Cancel” button to cancel saving

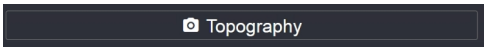
In which the birthday selection box is shown as below

Click the year or month to quickly select (shown as below).

Modify patient`s information: Click the Modify button to enter the editing interface. The method can refer to adding patient

Patient's information deletion: Select the patient information that needed to be deleted, and click the Delete button for deletion.

Create new patient`s information: Click the Capture button,

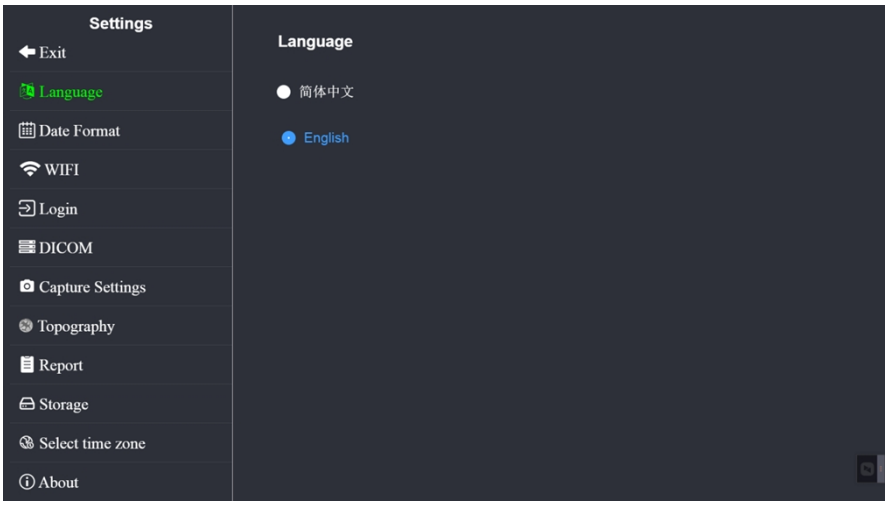


The case information will be auto-saved after testing.

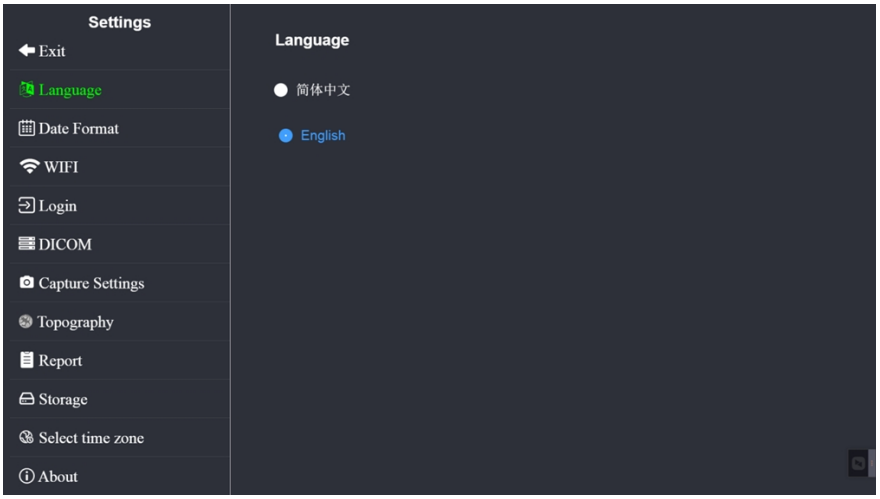
Case information deletion: Click the Delete button after each entry in the case list to delete the information.

3.2. System setting

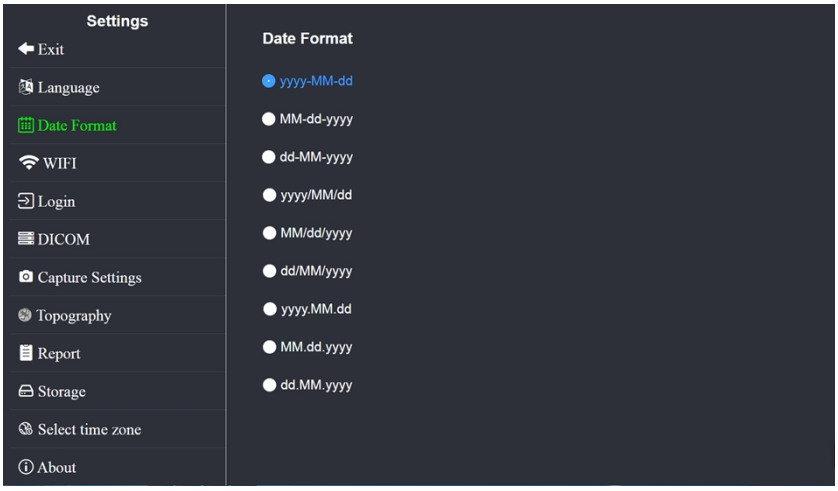
Click the setting button at the top right of the interface to enter the system setting interface (shown as below).



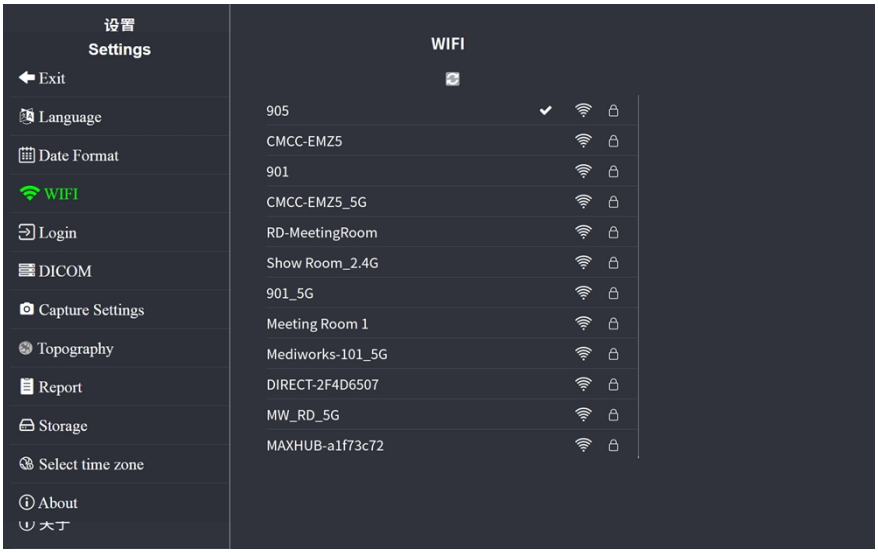
- Language Setting: Click the "Language" option to switch languages.



- Date Format: Click the "Date Format" option to choose the display of the date format

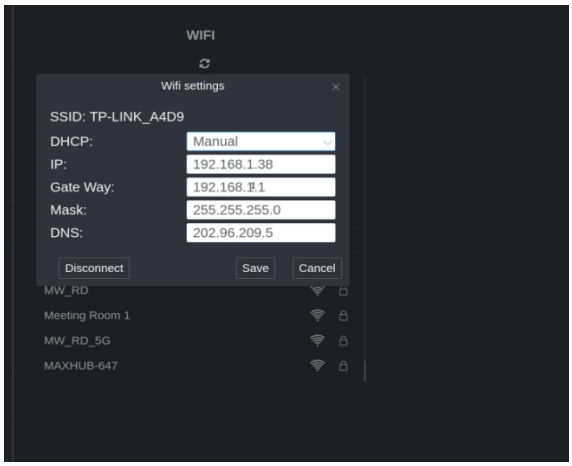


- WIFI Setting: Click the "WIFI" option to enter the WIFI interface.

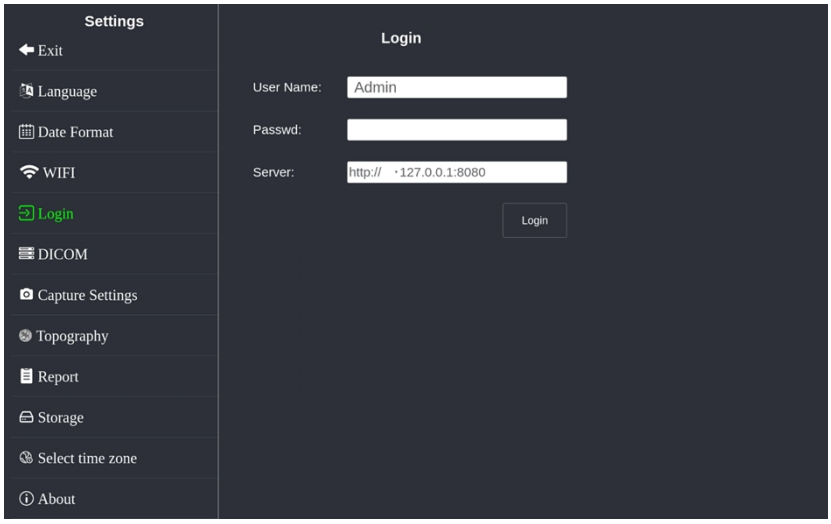


➢ WIFI Connection: Click the WI-FI that you want to connect, and input the WIFI password in the pop-up box.

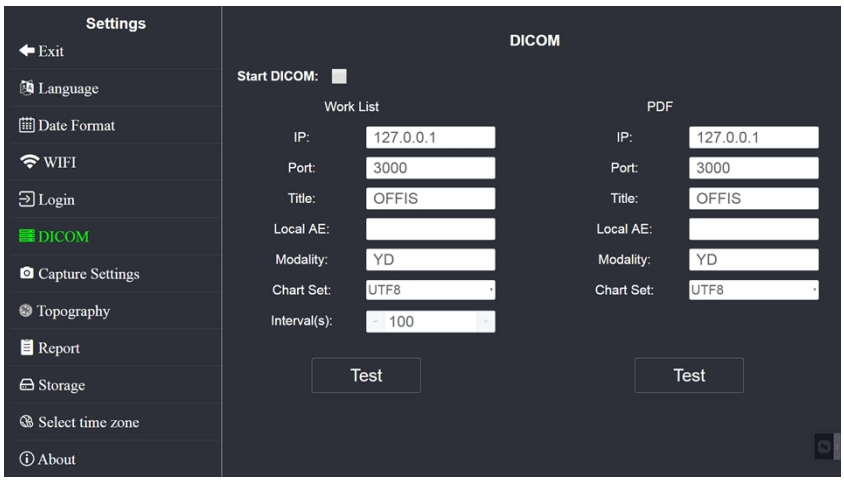
➢ WIFI Configuration: Click “Connected WIFI” to check or configure WIFI in the pop-up WIFI Configuration box.



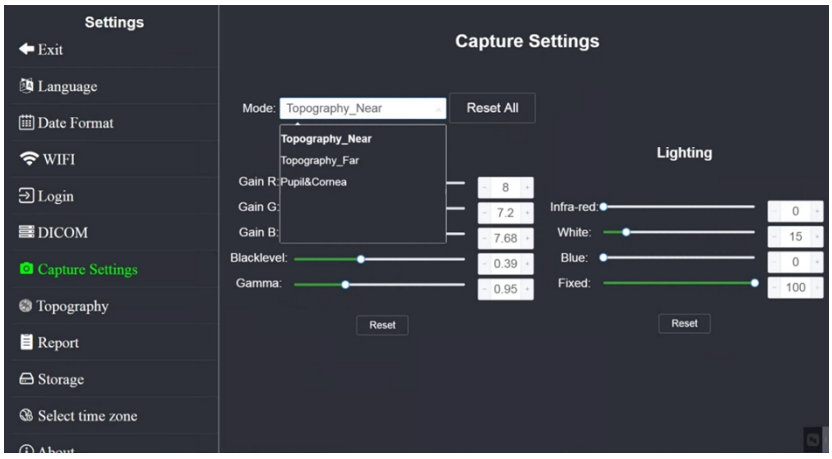
● Login: Click the "Login" option, Enter the IP address of remote equipment and user`s information in the input box then click login.



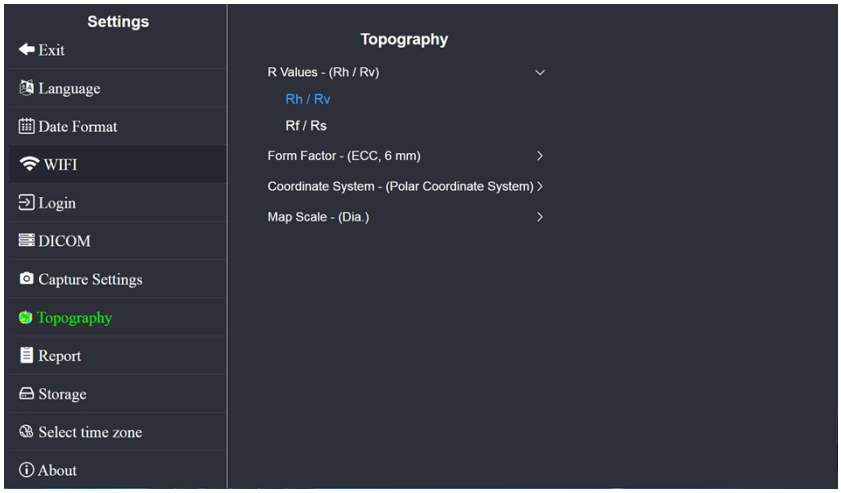
● DICOM: Click the "DICOM" option and enter the settings for the DICOM server.



● Capture Setting : Adjust parameters of camera and brightness of light in different Capture mode..

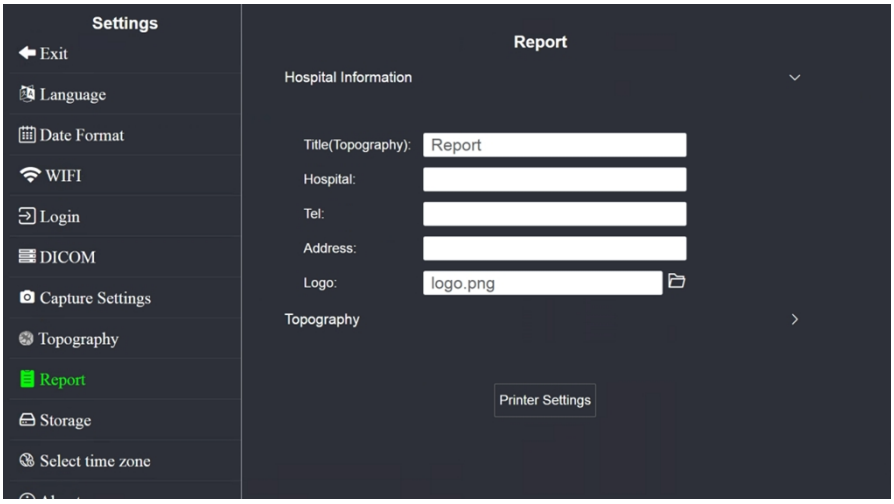


● Topography Setting : Select options you want to display in the topography map interface.

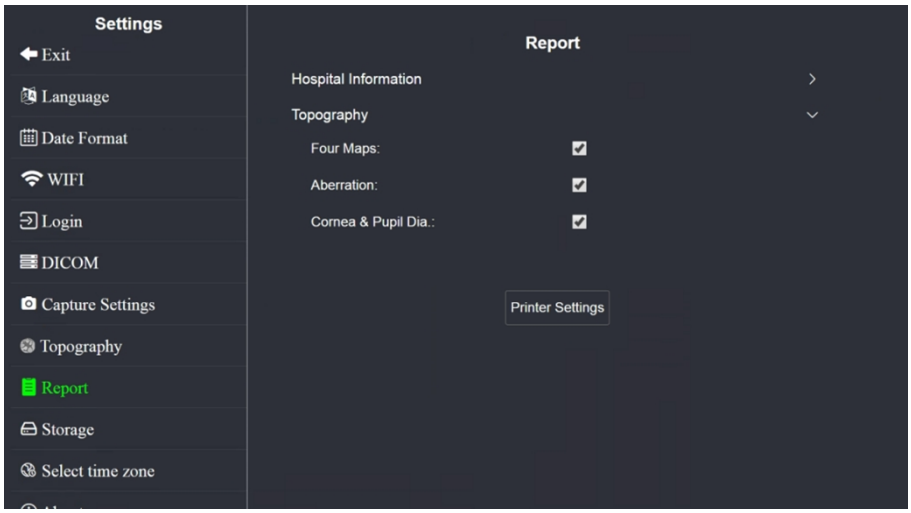


● Report: Click the "Report" option to enter the report setting interface.

1. Hospital basic Information: Enter the title of the report and the basic information of the hospital.

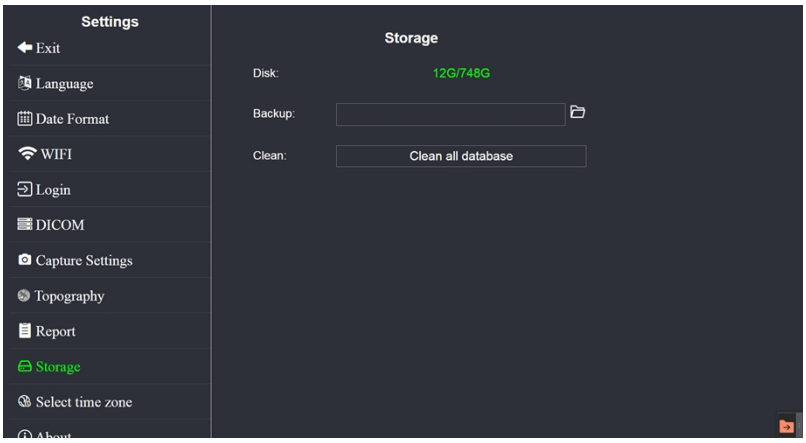


2. Topography: Select the module to print

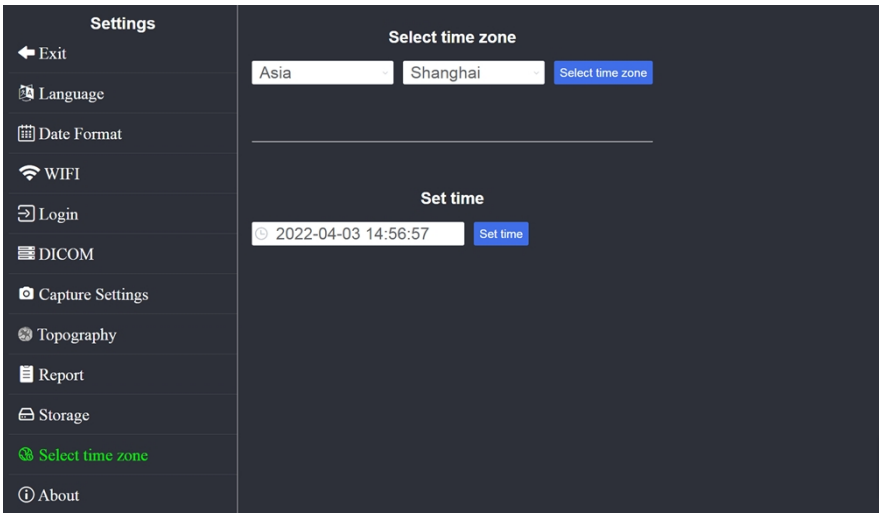


3. Printer Settings: Set up the printer.

● Storage: Check the drive usage, back up database, and delete the with one click



- Select time zone: Select time zone of system.



- About: Software version and copyright information

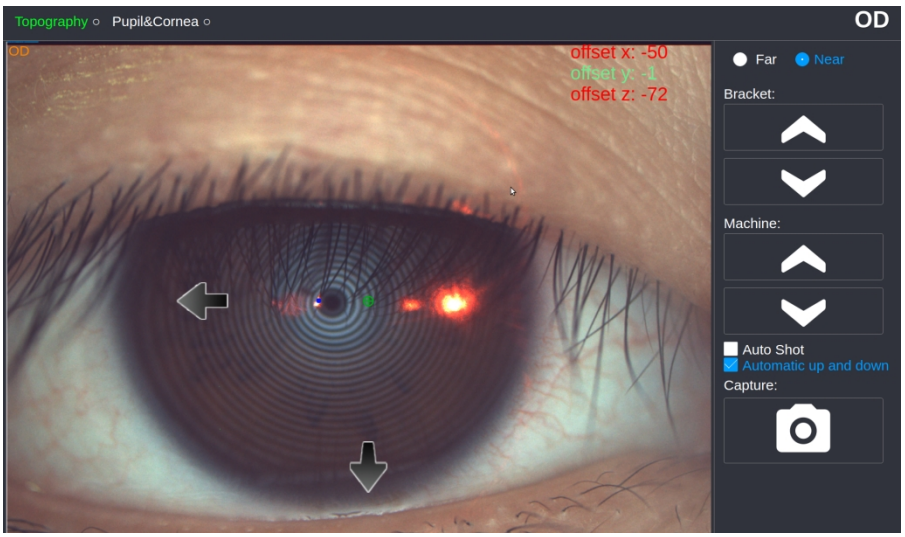
3.3. Corneal Topography Module

The functions of topography include: Capture, Topographic Map, Four Maps, Shape Factor, Aberration, Contact Lens, Pupil-Cornea, Case Comparison and Report.

3.3.1 Capture

After selection of a patient, click 

to start the Capture program and enter the Capture interface (shown as below).




Chin-rest lifting: Chin-rest Elevation Adjustment


Device lifting: Machine Adjustment

Automatic Capture: Automatically trigger Capture after focusing is completed.

Automatic up and down: Automatically adjust the height of the device.

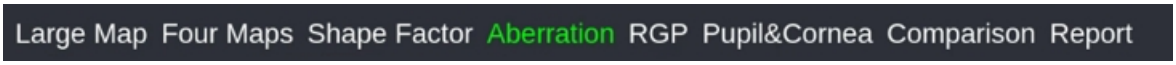
Manual Capture: Click the capture button on the interface or press the button on the handle.

Note: You can press the Capture button on the handle in any non-Capture interface to enter the Capture interface.

Method of Focusing:

- Adjust the height of chin-rest & DEA 520, move the joystick backward and forward, left and right, until the placido ring become clear in the interface.
- Let the patient keep his eyes widely open and look at the round fixed viewpoint.
- According to the indicating arrow on the interface, move the handle left and right, adjust the device position to move the green cross point to the center of the ring, move the handle back and forth, align the identified red laser point to the center of the green cross as the figure  , afterwards the Capture will be triggered automatically.

3.3.2 Function column



This part presents all the functional modules provided by the software with the detailed inspection results. Users can freely check the data under the corresponding functional modules according to their needs.

3.3.3 Characteristic data interpretation

Characteristic data shows corneal anterior surface.

Among them,

Rh / K1 represents the flat k-curvature radius and refractive power within a diameter range of 3mm, @ describes the direction.

Rv / K2 represents steep k-curvature radius and refractive value within a diameter range of 3mm, @ describes the direction.

Rm / Km represents the average radius of curvature and refractive power in the range of 3mm.

Astig represents astigmatism.

Ecc (E、Q、P） represents the corneal morphological factor value of a diameter ring with the apex of the cornea as the center of the circle.

Rmin / Kmax represents the minimum corneal radius of curvature and maximum refractive power, @ describes the position of the point.

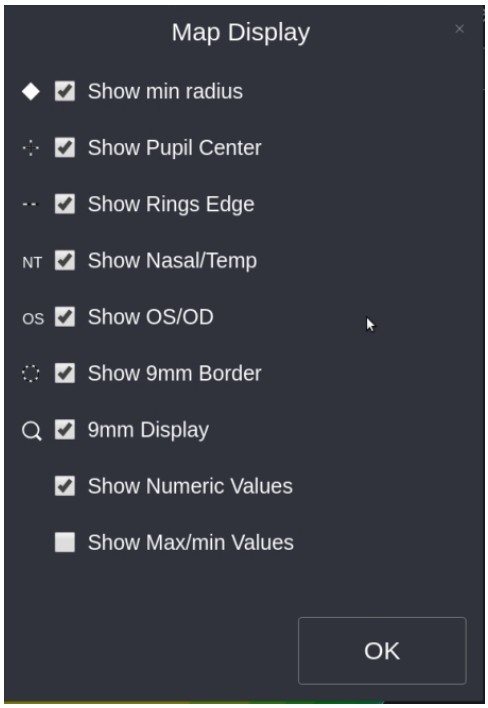
Other anterior segment parameters include pupil center, pupil diameter, etc.

3.3.4 Introduction of interface function of DEA520

When the image Capture is completed, the system automatically presents the results after calculation, which include topographic map, four maps, shape factor, and aberration coefficient.

3. 3. 4. 1 Topographic map

➢Topographic map display settings

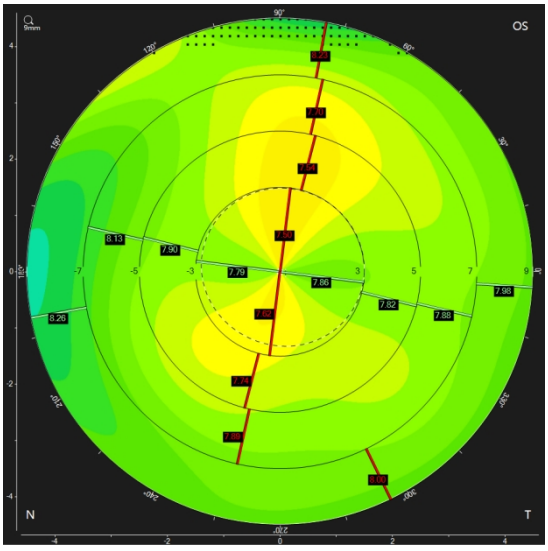


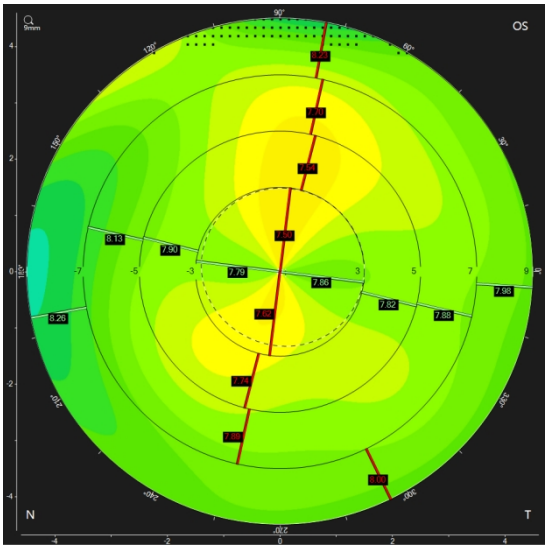
No matter in the Topographic Map Display Module, Four Maps Module or other modules, as long as there is an interface presenting topographic map, right-click or long-press on the topographic map can trigger on the topographic map display setting window. The function of displaying or not corresponding features on topographic map can be achieved by checking the feature box.

Where,

- Display the position of the minimum radius of curvature (anterior): The white solid diamond represents the maximum curvature point of the anterior surface of cornea;
- Display temporal side/nasal side: The letters "T" and "N" on the left and right sides at the bottom of the topographic map indicate temporal side and nasal side respectively, so as to facilitate distinction and positioning;
- Show left and right eyes: The top letters on the topographic map indicate "OS" as the left eye and "OD" as right eye, so as to facilitate distinction and positioning;

- Show 9mm boundary: White and black short dashed lines are used to represent a ring with a radius of 4.5 mm from the vertex;
- Show 9mm diameter topographic map: Only the topographic map of cornea diameter 9mm is available
- Display Maximum/Minimum values: Display the maximum and minimum values of the corresponding topographic map and their directions in the corneal diameter ranges of 3, 5, 7, 9 and 11mm. Besides, this setting item is only applicable to corneal sagittal curvature topographic map, tangential curvature topographic map and real net refractive topographic map.



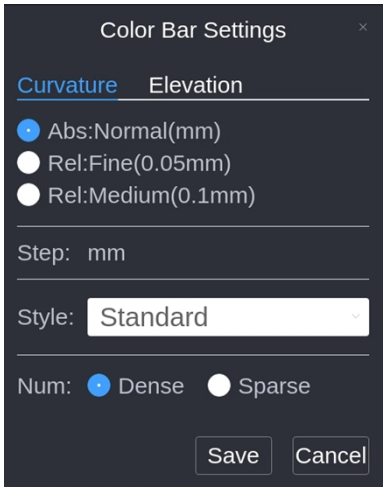


➢ Topographic map color bar setting

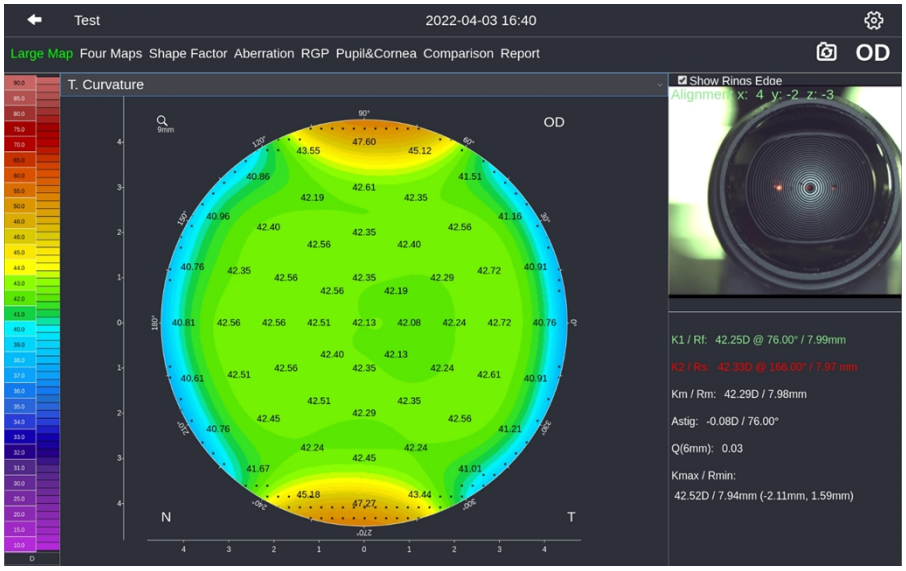
The topographic map is ultimately to use different colors to represent the overall distribution of data. the value of data is determined by the variant color bars on topographic map.

Each topographic map in the program will have the corresponding color bars. In addition, the color scale is marked on the color bar, below which there are the unit of the corresponding value of the current topographic map and the color bar mode (shown as below).

When click the color bar, the setting dialog box of current topographic map color bar will pop up. Users can change the color level interval (relative and absolute), color bar style, density degree, unit (only applicable to curvature-related topographic maps), and so on according to their own preferences or better reflect the changes of current topographic map.



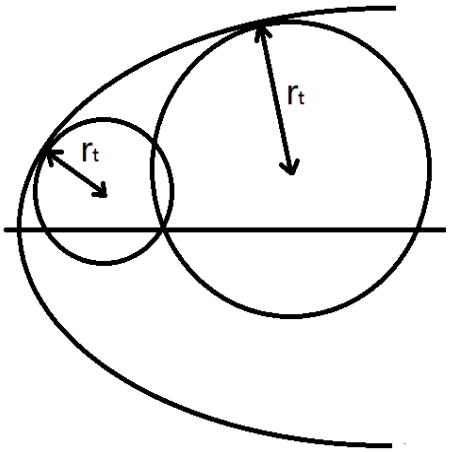
➢ Tangential curvature



The topographic map depicts the tangential radius of curvature at various points on the anterior surface of the cornea. The user can also click on the color bar to display it in diopter units.

The definition of the tangential radius of curvature at a point: find the radial arc passing through the point and the apex of the cornea and calculate as follows

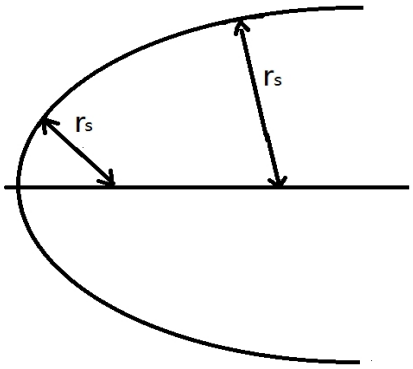
The geometric irregularities of the cornea are more pronounced in this mode.



➢ Sagittal curvature

The topographic map depicts the Sagittal radius of curvature at each point on the anterior surface of cornea. You can also click on the color bar to set it tas presenting in dioptre units.

Definition of sagittal radius of curvature at a certain point: After the radial arc passing through this point and corneal apex is found, it is calculated according to the following definition

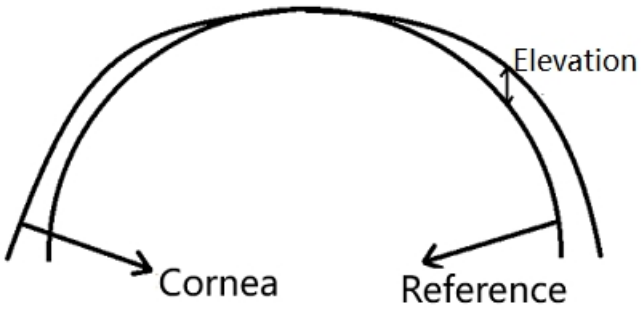


The radial (or Sagittal) curvature is equivalent to the distance between the measuring point and the intersection of the perpendicular to the tangent of the measuring point and the axis. In the radial representation mode, the curvature value depends on the inclination of the measurement point. At the same time, the position of the optical axis should also be considered. Sagittal display mode provides the better analysis on the impact of cornea on visual acuity of patients.

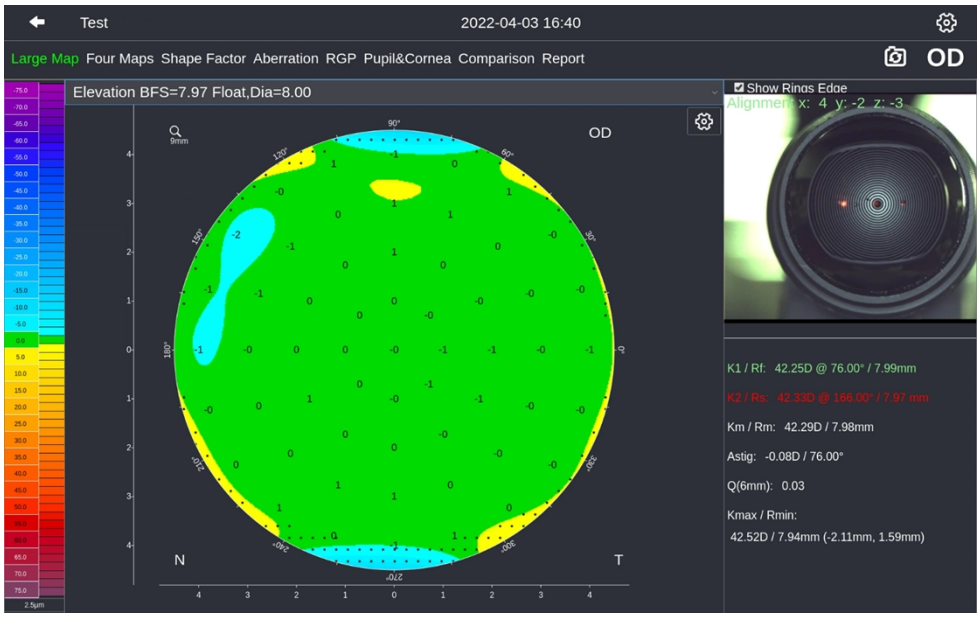
- Elevation Map

Description of Elevation Map

In terms of the elevation, there must be a reference, namely a relative object, which can be a plane or any curved surface. The height topographic map is described by the difference between cornea and reference.



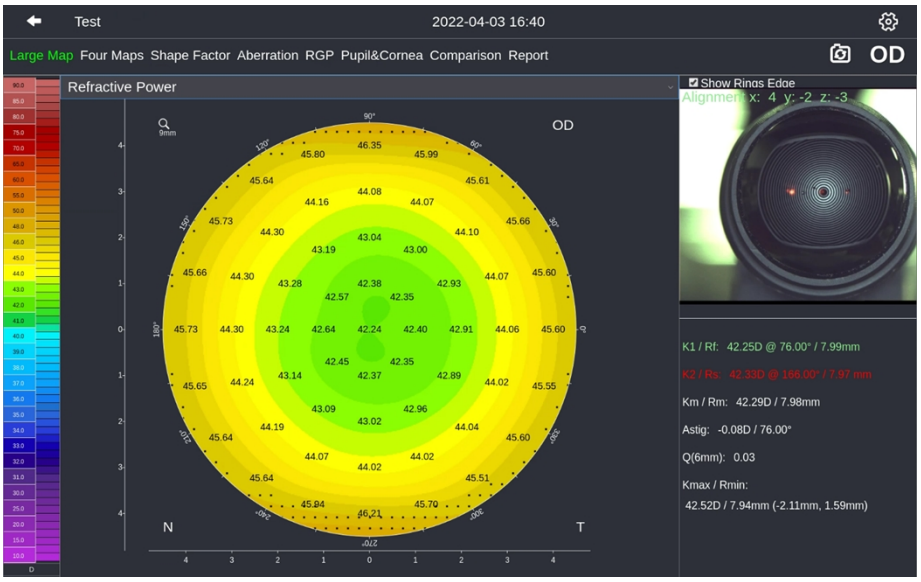
The value can be positive (cornea higher than reference) or negative (cornea lower than reference).



The topographic map depicts the elevation data of the anterior corneal surface.

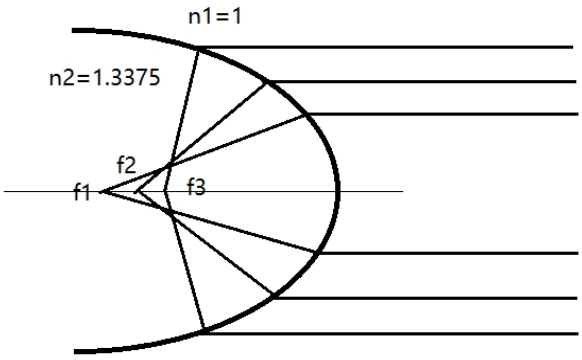
The elevation here is a relative concept. The specific meaning refers to the explanation of elevation data and reference in the previous section. BFS in the topographic map title represents the Best Fit Spherical radius of the anterior corneal surface data, while Dia represents the minimum sampling diameter sampled to the cornea.

➢ Refractive Power Map



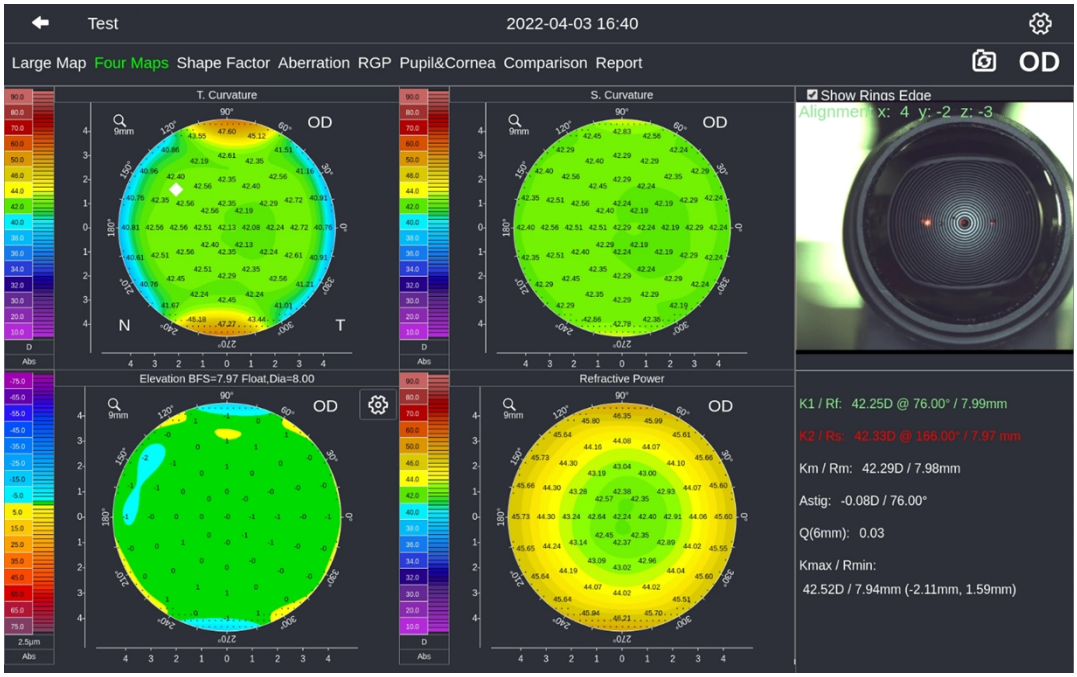
In order to estimate the optical effect of anterior corneal surface, the topographic map uses focal length instead of curvature value to calculate refractive power. According to Snell's law (ray tracing method), the focal length is calculated to consider the influence of spherical aberration. Assuming a standard sphere, the refractive power difference under this definition is very obvious compared with the traditional curvature topographic map

1. The curvature diagram shows only one refractive power, because the curvature of each point of the sphere is the same.
2. Given the spherical aberration effect, the refractive power at the periphery (F3) of the refractive diagram under this definition will be too large, while the refractive power at the middle (F1) will be too small.



3. 3. 4. 2 Four Maps

Click on the menu "Four Maps" to open the interface containing corneal sagittal curvature map, tangential curvature map, elevation map, and corneal curvature refractive diagram (see figure below).



The presentation of four topographic maps is fixed, which can assist general ophthalmologists in diagnosing corneal abnormalities.

3. 3. 4. 3 Shape Factor module

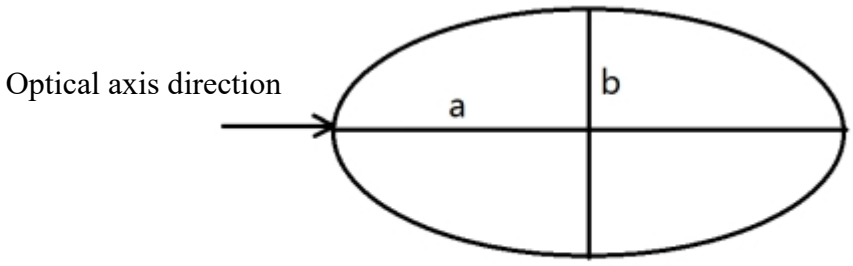
Click the " Shape Factor" option to enter the Shape Factor function module.

This module shows the tangential and sagittal curvature topography of cornea.

The above chart describes the corneal shape factors and the curvature values of the anterior and posterior corneal surfaces at each radial sagittal ring and the intersection of the four radial directions.

Corneal shape factors include Ecc, E, Q and P, which can be changed in shape factor presentation of "topographic map and data display settings" in menu bar..

The cross section of corneal is not an ellipse in the strict sense, so that it is necessary to find the best fitting ellipse in a certain direction in calculation. The following definitions of various shape factors are described based on the definition of ellipse.



3. 3. 4. 4 Shape factor

➢ Ecc

It is the standard mathematical definition of elliptical Eccentricity, and the calculation formula is

$$e = \sqrt{1 - \frac{\min(a,b)^2}{\max(a,b)^2}}$$

It is noteworthy that the Eccentricity E cannot distinguish whether it is a flat ellipse or not.

➢ P

The purpose of this shape coefficient is to resolve the limitation of Ecc value, which can be defined as

$$P = \frac{b^2}{a^2}$$

Using this shape coefficient, we can describe a circle as p=1, a flat ellipse with p value less than 1, and a circular ellipse with p value greater than 1.

➢ Q

The shape coefficient can be used to express what the deviation is between a specific curve and the sphere It is defined as

$$Q = P - 1$$

The Q value of spherical surface is 0, the Q value of oblate ellipse is negative, and the Q value of circular ellipse is positive.

➢ E

The shape coefficient is similar to Q value, but the difference lies in that the value of flat ellipse is positive, while that of circular ellipse is negative. It can be defined as

$$E = 1 - \frac{b^2}{a^2}$$

Shape coefficients are conductive to partially quantifying eye shape characteristics. These coefficients are calculated from an ellipse approximating a specific cross-section of the eye (usually a steep or flat axis). The applicability of these attributes is described in details in the article “Corneal Asphericity: The e's, p's and Q's of Corneal Shape” by Swarbrick, H. in Refractive Eyecare for Opthalmogologists, December 2004.

The figures at the bottom presents the average value of corneal shape factors at corneal astigmatism.

3.3.4.5 Aberration

➢ Overview

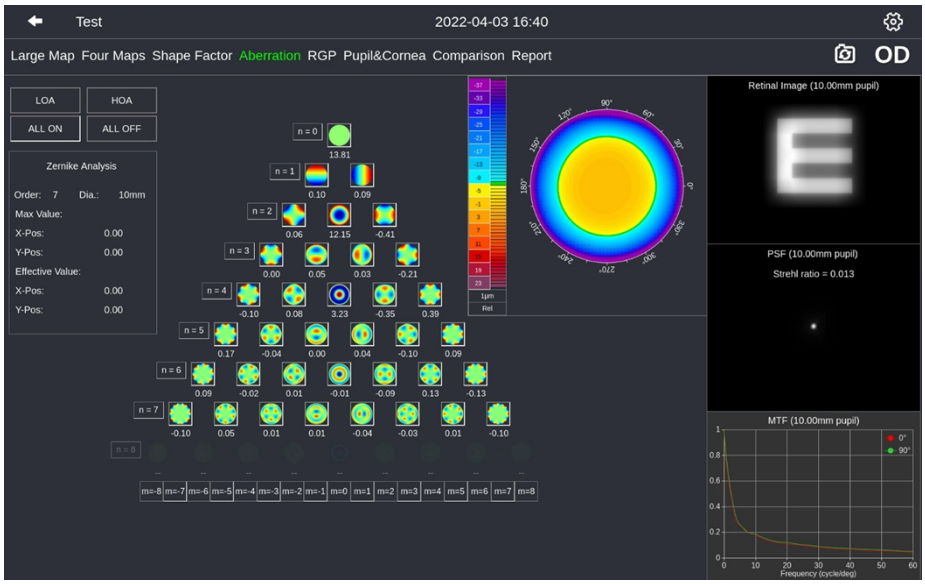
- Zernike polynomials are commonly used to describe wavefront, each beam containing a sinusoidal oscillation, and points in the entire sinusoidal oscillation array having the same phase direction form a refractive surface that is perpendicular to the plane wavefront of the propagation direction. In the ideal case, the incident wavefront juxtaposed to each other are deformed to form a spherical wave that accurately satisfies the focal length F. But this ideal situation will not occur because the true wavefront display is different from the perfect refractive spherical wave.
- When the deviation or aberration is smaller, the quality of the refractive system is higher. The Dutch physicist and Nobel laureate Frits Zenike (1888-1966, the inventor of the aberration microscope) successfully gave a mathematical representation of the true wavefront and ideal deviation by polynomial fitting. Each polynomial is named according to the image defect represented (eg. coma, spherical aberration). Zernike polynomials are also known as ring polynomials because they refer to circles with a radius of 1, expressed in polar coordinates.

From a mathematical point of view, each Zernike polynomial is represented by a product of multiple powers of radius r and multiple powers of angle variable θ.

- A Zernike polynomial has the following definition:
- Z0, 0 height constant, average surface height
- Z1, ±1 tilt (x direction +1, y direction -1)
- Z2, 0 conical part shape focal length or surface
- Z2, ±2 astigmatism
- Z3, ±1 coma
- Z3, ±3 trilobal
- Z4, 0 spherical aberration
- Z4, ±2 high order (4) astigmatism
- Z4, ±4 four-leaf defect
- Z5, ±1 high order (5) coma
- Z5, ±3 high order (5) trilobal
- Z5, ±5 five-leaf defect
- Z6, 0 high order (6) spherical aberration
- Z6, ±2 high order (6) astigmatism
- Z6, ±4 high-order (6) four-leaf defect
- Z6, ±6 six-leaf defect

- Aberration analysis

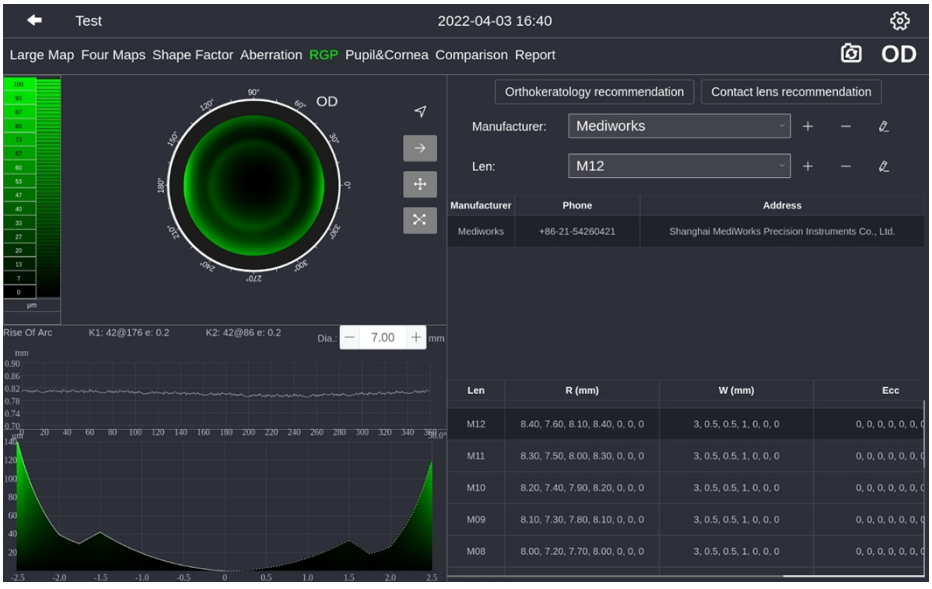
Click on the left section to start the DEA520 “Aberration” analysis function. As follows,



This view is an aberration analysis based on the measured elevation data of the anterior and posterior corneal surfaces. It calculates a coefficient for each aberration polynomial term, which describes the contribution of this polynomial to the elevation data.

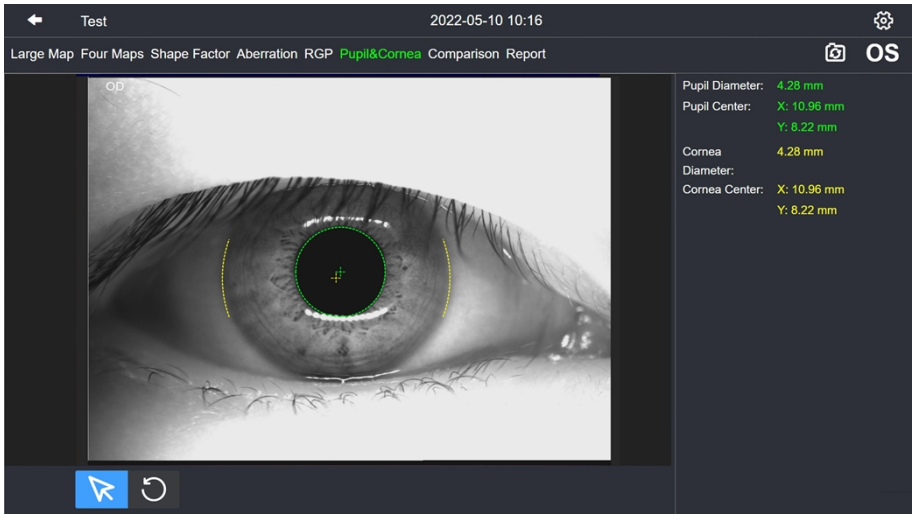
3. 3. 4. 6 RGP

This module is used for RGP fitting. Input the lens parameters, simulate the trial wearing and recommend the characteristics of Orthokeratology lens.



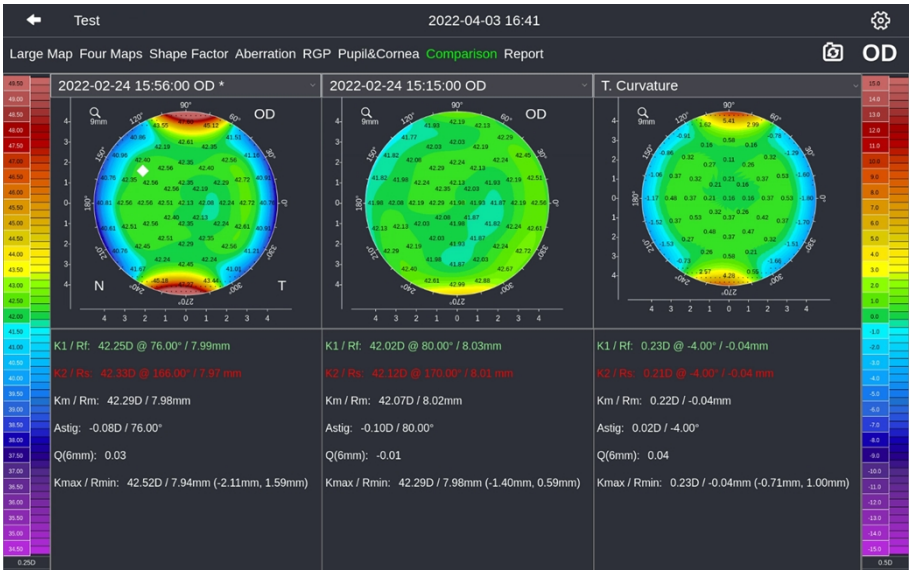
3. 3. 4. 7 Pupil&Cornea

In the interface below, the green circle identifies the pupil and the yellow arc identifies the cornea. The right side shows pupil diameter and pupil center coordinates, corneal diameter and corneal center coordinates respectively.

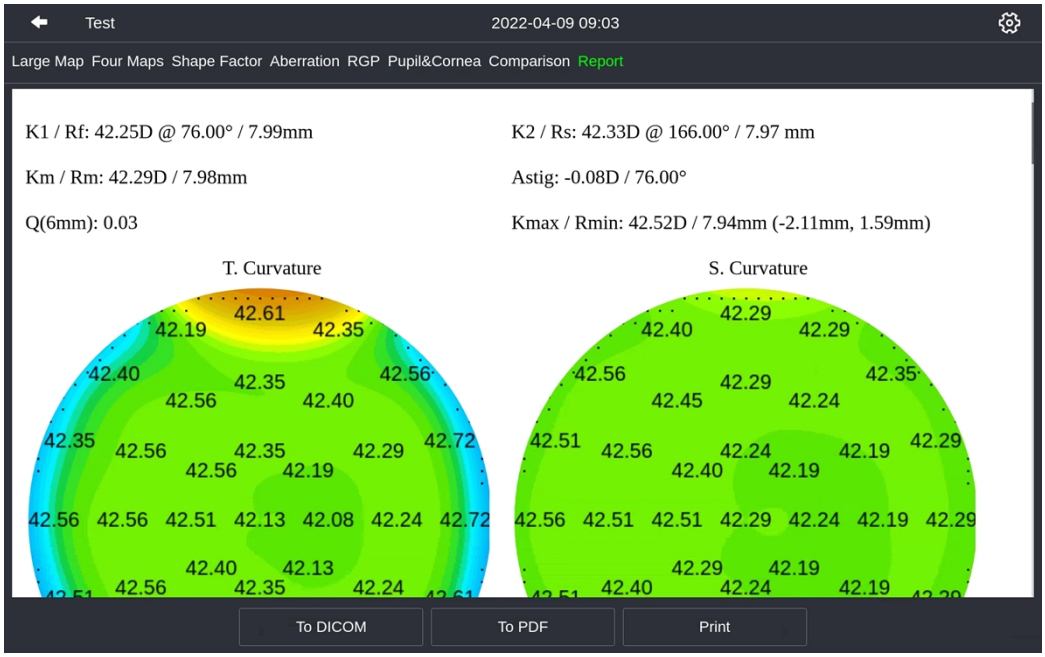


3. 3. 4. 8 **Comparison of two inspections**

Click the "Comparison" function button in the menu to compare both eyes or compare the examination results of the same eye at different times.



3. 3. 4. 9 Report



Click the menu "Report" function button, then a report will be generated according to the selection.

➢Click the "Print" button to print the report.

➢Click the "To DICOM" button to pop up the file selection window, select the desired PDF file to the DICOM server

➢Click the "To PDF" button to output PDF

4. Product cleaning and maintenance

4.1. Cleaning Methods

1. Cleaning and disinfecting plastic parts: To clean plastic parts such as Chin-rest and forehead bracket, dip soft cloth in soluble detergent or water to clean dirt, and then wipe it with medical alcohol for disinfection. Note: Do not use any corrosive cleaning agent to wipe, so as not to damage the surface.

2. Cleaning the placdio ring: The Placdio ring is a precise optical element. Please be gentle in cleaning process. You can use a soft cloth dipped in distilled water or sterile water for injection to clean it. Note: Since the Placdio ring is not resistant to alcohol or

other organic solvents, so please do not wipe with alcohol/ organic solvents/ any corrosive cleaning agents, and do not touch with sharp objects to avoid damage.

3. Cleaning the surface of the device: Dip a soft cloth with soluble detergent or water to clean the dirt. Do not use any corrosive cleaning reagent to wipe, so as not to damage the surface.

4. Replacing Chin-rest paper: When the Chin-rest pad paper is used up, pull out the two fixing bolts on the Chin-rest upward, put on the new pad of paper, and then install the fixing bolts.

Note: Do not use diluent and other organic solvents or corrosive cleaning reagents to clean the device, so as to avoid any damage.

4.2. Product Cleaning Cycle

DEA520 device should be used in a relatively clean environment. In order to ensure the normal use and observation of DEA520, the operator should clean it regularly. The cleaning interval is recommended as follows:

1. For Placido ring:

Cycle: Every 2 months . (Recommened).

Placido ring is used for projection on the surface of human eyes. If there are a lot of dust adhered to Placido ring, which has reduced the observation quality, it is recommended to clean it immediately according to the specified methods.

2. For plastic parts, such as Chin-rest and forehead bracket:

Cycle: It is recommended to clean after testing of every patient.

These two parts are frequently in contact with the inspected person, which should be cleaned and disinfected in regular cycle. The cleaning and disinfection cycle is only our suggestion; After each examination, the forehead support belt shall be cleaned and disinfected while the Chin-rest paper shall be changed.

3. For the whole device

Cycle: Every 2 months.(Recommened).

4.3. Product Maintenance Cycle

The model eye should be used regularly to inspect the device, to ensure that the device is in a good operating condition.

When the device is not used, please put the device with a dust cover;

When the device is not used for a long time, the power supply should be cut off.

When the device needs to be transported, it is necessary to locate the jack to the lowest position and lock the transport lock, otherwise the equipment may be damaged

5. Trouble Shooting

If there is a malfunction, please check it according to the guidance in the table below. If the malfunction cannot be eliminated, please contact MediWorks Service Department or the authorized dealer.

Malfunction	Possible Cause	Countermeasures
Do not boot up	The power cord is not properly connected to the power outlet	Connect the power cord correctly
	The main power switch is in the O position	Put the switch in the I position

Cannot capture clearly	The projection area of Placido ring may be insufficient due to the deep eye socket	Adjust the sitting posture of the patient slightly and skew slightly to avoid interference of brow bone or nose bridge

Production Date : See label

Service Life: 8 years

Version:1.0

20220506

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